

SOP Number: <b>ITCSOP-000637</b>	Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>	

## 1 PURPOSE / SCOPE

- 1.1 This procedure defines the step-by-step mechanical and electrical tests to verify that the **Infiniti®** Vision System is performing to specifications.
- 1.2 The Service Functional Test procedure is used to ensure the **Infiniti®** Vision System meets specifications after installation of the unit, after repairs are made, and after routine preventative maintenance. Form ITCDOC-000360, *Data Sheet for Infiniti Vision System*, must be filled out completely.
- 1.3 The check mark in a box (☑) symbol indicates that an entry is required on Form ITCDOC-000360, *Data Sheet for Infiniti Vision System*. The entry can be either a ✓, or requested data. A "N/A" is to be used when a verification step could not be completed, and MUST be noted at the end of Form ITCDOC-000360, *Data Sheet for Infiniti Vision System*. If a PM is performed in conjunction with a repair or upgrade, only the Preventative maintenance box is to be checked on Form ITCDOC-000360, *Data Sheet for Infiniti Vision System*.

## 2 PROCEDURE

**NOTE:** Refer to **Infiniti® Vision System Service Manual** for recommended tools, equipment, disassembly instructions, part locations and troubleshooting.

**CAUTION:** To prevent electrostatic discharge (ESD) damage, be sure to wear grounded wrist strap when handling individual PCB assemblies outside the system.

### 2.1 PREVENTATIVE MAINTENANCE CHECK

**NOTE:** This procedure is to be performed on the system and its accessories a minimum of one time per year.

**NOTE:** It is allowable to alter the order in which the following Preventative Maintenance Steps are conducted.

- 2.1.1 ☑ Inspect and clean the front panel touchscreen.
  - 2.1.1.1 Look for cracks or other physical damage to the front panel touchscreen and replace if necessary.
  - 2.1.1.2 Inspect and clean as necessary, touchscreen with damp cloth or nonammonia based window cleaner.
- 2.1.2 ☑ Verify Front Panel Display pivots (up & down), swivels (left & right) and rotates (270°) smoothly, without requiring so much force as to move the system (with front casters locked), and enough force is required that the display does not move when pressing touch screen.
- 2.1.3 ☑ Remove the necessary panels to inspect and clean, as required, the accessible internal console cavities of the Infiniti™ system.
- 2.1.4 ☑ Check the ground resistance of chassis/power cord.
  - 2.1.4.1 Set the meter to measure resistance and attach the two test leads together. Normalize the leads so the meter displays 0 ohms or record the measured (displayed) resistance and subtract it from the measured resistance below to get actual ground resistance.
  - 2.1.4.2 If system is on, shut down and turn OFF AC Power Switch.
  - 2.1.4.3 Set Scope meter to measure resistance from 24VRTN(TP2) on System Power Distribution PCB to Chassis.
  - 2.1.4.4 Verify DVM reading <0.5 ohm.
  - 2.1.4.5 Connect one meter lead to AC cords ground lug and then the second lead to phaco or host system card cage.
  - 2.1.4.6 Verify DVM reading <0.5 ohm.

Status:	<i>Effective</i>	Supersedes:	<i>SOP-0637</i>
---------	------------------	-------------	-----------------

SOP Number: <b>ITCSOP-000637</b>	Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>	

2.1.5 ☒ Inspect system hardware.

2.1.5.1 Check condition of handpiece connectors, tray & arm assemblies, Front panel, and outside body of system. Ensure nuts, bolts, and screws are tight. Clean, repair, or replace as necessary.

2.1.6 ☒ Visually inspect all cables, connectors, PCB's, Panels and covers. Replace footswitch cable as necessary.

2.1.7 ☒ Check and tighten all four casters (console wheels).

2.1.8 ☒ Use a finger to check that all four Fluidics module hub rollers spin freely.

2.1.9 ☒ System Cooling

2.1.9.1 Turn on AC Power switch (lower rear of unit) and then the Standby switch (upper rear of unit).

2.1.9.2 Verify 2 system fans are running. (Note: 2 Power Supply fans cannot be checked without removing covers).

2.1.9.3 Inspect and clean air filter above tray arm area.

2.1.9.4 Inspect and clean filters on each lower skin

2.1.10 ☒ IV Pole Test

2.1.10.1 Move the IV pole up and down to its limits looking and listening for stalling and vibration.

2.1.11 ☒ CPC Connector

2.1.11.1 Inspect CPC connector and connector "O" rings for signs of wear. Replace connector as required.

2.1.12 ☒ Pneumatic Line Filters

2.1.12.1 Inspect pneumatic line filters for excessive deposits and replace filters as necessary.

2.1.13 ☒ Install Covers

2.1.13.1 Replace all system covers removed in previous steps.

2.1.14 ☒ Video Output Test

2.1.14.1 Perform step 2.2.12.

2.1.15 Replacement of CPU PCB Lithium Battery

2.1.15.1 Replace the battery per instruction in the Infiniti® Service Manual unless the system date of manufacture or the CPU battery replacement has occurred in the previous three years.

2.1.16 Replacement of 12 Volt Lead-Acid Battery

2.1.16.1 Replace the battery per instruction in the Infiniti® Service Manual unless the system date of manufacture or the back-up battery replacement has occurred in the previous five years.

## 2.2 SERVICE FUNCTIONAL TEST

**NOTE: It is allowable to alter the order in which the following Service Functional Test steps are conducted.**

### 2.2.1 FRONT PANEL TEST

#### 2.2.1.1 DISPLAY

2.2.1.1.1 Turn ON AC Power switch (lower rear of unit) and then the Stand-By switch (upper rear of unit)

2.2.1.1.2 ☒ Verify that display shows Setup screen.

Status:	<i>Effective</i>	Supersedes:	<i>SOP-0637</i>
---------	------------------	-------------	-----------------

SOP Number: <b>ITCSOP-000637</b>	Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>	

### 2.2.1.2 TOUCH SCREEN/TONE/VOICE



**Figure 1: Touchscreen Example**

- 2.2.1.2.1 Select 'Alcon Settings' from the list of surgeons. Select 'Handpiece', 'Tip', 'Procedure' and 'Grade' from the Setup screen menu and verify that each has a drop down menu with a list of options provided.
- 2.2.1.2.2 Proceed to the surgical screen and in turn select each step in the surgical procedure and check for changing parameters:
- 2.2.1.2.3 ☒ Verify procedural steps can be selected.
- 2.2.1.2.4 ☒ Verify tone/voice responses.

### 2.2.1.3 CONTROL BUTTONS

- 2.2.1.3.1 Select the first surgery step in the procedure. Test control of displayed limit adjustment arrows for up/down control of setting.
- 2.2.1.3.2 ☒ Verify Adjust Button (see Fig. 1) produces button(s) in middle of screen when selected.

### 2.2.1.4 MULTIMEDIA CARD DRIVE (Backup/Delete/Restore)

- 2.2.1.4.1 ☒ Perform the following steps to backup data from Infiniti™ to Data Card.
  - 2.2.1.4.1.1 Press Doctor Name (Alcon Settings) button in upper-left corner of screen.
  - 2.2.1.4.1.2 Select Add Doctor from drop down list, (Press "Discard") type TEST DOC on keyboard, then press OK.
  - 2.2.1.4.1.3 Select Ultrasound (U/S) handpiece, OK, and Cataract Grade 1.
  - 2.2.1.4.1.4 Press Surgery button to enter surgery screen, select Ultrasound Continuous and set Power Limit to 50.

Status:	<i>Effective</i>	Supersedes:	<i>SOP-0637</i>
---------	------------------	-------------	-----------------

SOP Number: <b>ITCSOP-000637</b>	Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>	

- 2.2.1.4.1.5 Press the Custom button, then Save...The dialog "Save changes to the surgical step parameters of the current doctor?" appears. Press the Save button to save new doctor named TEST DOC in Infiniti™.
- 2.2.1.4.1.6 Insert data card into its slot on the right side of the Infiniti™ below the speaker.
- 2.2.1.4.1.7 Press the Custom button, then Copy/Delete...
- 2.2.1.4.1.8 Press the top-left source pane button to select INFINITI™. Select TEST DOC.
- 2.2.1.4.1.9 Press the top-right pane button to select DATA CARD, then select Doctors if there are Dr. memories already on the card.
- 2.2.1.4.1.10 Press the Backup arrow button in the top-center of the screen twice. The system archives the TEST DOC data from the Infiniti™ to the data card.
- 2.2.1.4.2 ☒ Perform the following steps to delete TEST DOC data from Infiniti™.
  - 2.2.1.4.2.1 Press Exit to leave Copy/Delete screen and return to surgery screen.
  - 2.2.1.4.2.2 Press TEST DOC and select Alcon Settings from the drop down list.
  - 2.2.1.4.2.3 Press the Custom button, then Copy/Delete...
  - 2.2.1.4.2.4 Press the top-left source pane button to select INFINITI™. Select TEST DOC.
  - 2.2.1.4.2.5 Press Delete in the lower-left corner of the screen then "O.K.". The dialog "Permanently delete selected doctor settings?" appears. Press the OK button.
  - 2.2.1.4.2.6 Press Exit to leave Copy/Delete screen and return to surgery screen.
  - 2.2.1.4.2.7 Press Alcon Settings and verify TEST DOC has been deleted from Infiniti™ drop down list.
- 2.2.1.4.3 ☒ Perform the following steps to restore TEST DOC data from Data Card to Infiniti™.
  - 2.2.1.4.3.1 Press the Custom button, then Copy/Delete...
  - 2.2.1.4.3.2 Press the top-left source pane button to select DATA CARD.
  - 2.2.1.4.3.3 Press Doctors and select TEST DOC (with date shown in lower left corner).
  - 2.2.1.4.3.4 Press the top-right destination pane button to select INFINITI™.
  - 2.2.1.4.3.5 Press the Restore arrow button in the top-center of the screen. The system restores the TEST DOC data from the data card to the Infiniti™
  - 2.2.1.4.3.6 Press Exit to leave Copy/Delete screen and return to surgery screen.
  - 2.2.1.4.3.7 To verify transfer of TEST DOC cataract grade 1 settings to Infiniti™, press Alcon Settings, select TEST DOC, press U/S, press U/S Continuous, press cataract grade 1 button, and verify Power Limit is 50.
- 2.2.1.4.4 ☒ Perform the following steps to delete TEST DOC from Data Card
  - 2.2.1.4.4.1 Press the Custom Button, then Copy/Delete...
  - 2.2.1.4.4.2 Press the top-left source pane button to select DATA CARD.
  - 2.2.1.4.4.3 Press Doctors and select TEST DOC.
  - 2.2.1.4.4.4 Press Delete in the lower-left corner of the screen. The dialog "Delete doctor backup on Data Card" appears. Press the Ok button and then exit to surgery screen.
  - 2.2.1.4.4.5 Remove data card from its slot.
- 2.2.1.4.5 ☒ Repeat 2.2.1.4.2.2 to 2.2.1.4.2.7, Delete TEST DOC data from Infiniti™
- 2.2.2 **REMOTE CONTROL TEST**
  - 2.2.2.1 Hold Remote Control about 5 feet from Front Panel of system.  
***NOTE: Remote receiver windows are located at top Front Panel.***
  - 2.2.2.2 Press buttons to change functions/steps.
  - 2.2.2.3 ☒ Verify that system changes between selected functions/steps.

Status:	<i>Effective</i>	Supersedes:	<i>SOP-0637</i>
---------	------------------	-------------	-----------------

SOP Number: <b>ITCSOP-000637</b>	Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>	

### 2.2.3 FLUIDICS MODULE TEST

#### 2.2.3.1 FMS AUTO-LOAD

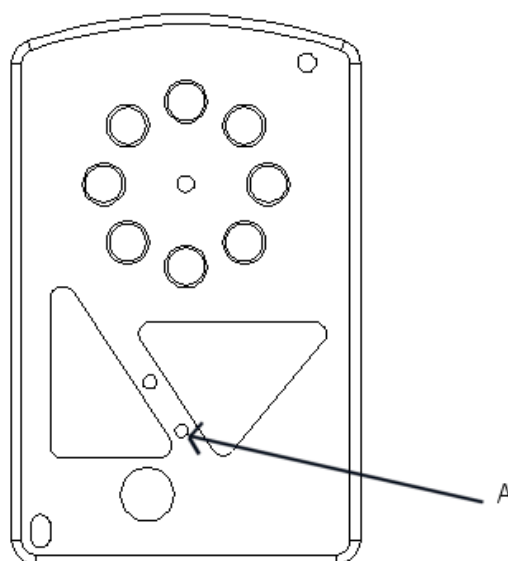
- 2.2.3.1.1 Press Setup to go back to Setup screen.
- 2.2.3.1.2 Install service test FMS into Fluidics subsystem.
- 2.2.3.1.3 ☒ Verify FMS latch mechanism pulls FMS into position and FMS remains latched.
- 2.2.3.1.4 ☒ Press CUSTOM button, ABOUT. Record REL\_# and then press SERVICE.

#### 2.2.3.2 ASPIRATION SENSOR CALIBRATION

- 2.2.3.2.1 ☒ Verify display "FMS calibration passed." If necessary eject and reinsert test FMS.

#### 2.2.3.3 IRRIGATION FAILSAFE

- 2.2.3.3.1 Press OPEN IRRIGATION VALVE button on Service screen.
- 2.2.3.3.2 Place small plastic alignment tool (blunt end) through IRR hole in test FMS (Marked "A" in Figure 2). And hold with force to restrict valve plunger from moving.



**Figure 2:** Test FMS, IRR Plunger Location

- 2.2.3.3.3 Press CLOSE IRRIGATION VALVE button on front panel.
- 2.2.3.3.4 ☒ Verify fault "Fluidics Failed; Ultrasound, Pneumatic, and AquaLase™ Offline" messages. Press "Restart" then "OK"
- 2.2.3.3.5 Remove service test FMS.

### 2.2.4 FOOTSWITCH TEST

- 2.2.4.1 ☒ Select Surgery. Verify footswitch icon (located in upper part of display) indicates position 0.
- 2.2.4.2 Select Coag mode, switch to Linear control, and increase preset maximum power to 100%.
- 2.2.4.3 Watch the footswitch icon while slowly depressing the pedal. Verify the following:
  - 2.2.4.3.1 ☒ Observe the change from position 0 to 1 then 2.
  - 2.2.4.3.2 ☒ Observe the actual Coag power increases from 0% to 100% as the pedal is depressed.
- 2.2.4.4 ☒ While depressing the footpedal, move and flex the footswitch cable and verify that there is no intermittent response to Coag power or the footswitch icon.
- 2.2.4.5 Select Alcon Settings. Select **any surgical** step. Select Footswitch icon, **Treadle**, and turn Vibration on. Increase level to maximum setting. Press Save, then OK.

Status:	<i>Effective</i>	Supersedes:	<i>SOP-0637</i>
---------	------------------	-------------	-----------------

SOP Number: <b>ITCSOP-000637</b>	Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>	

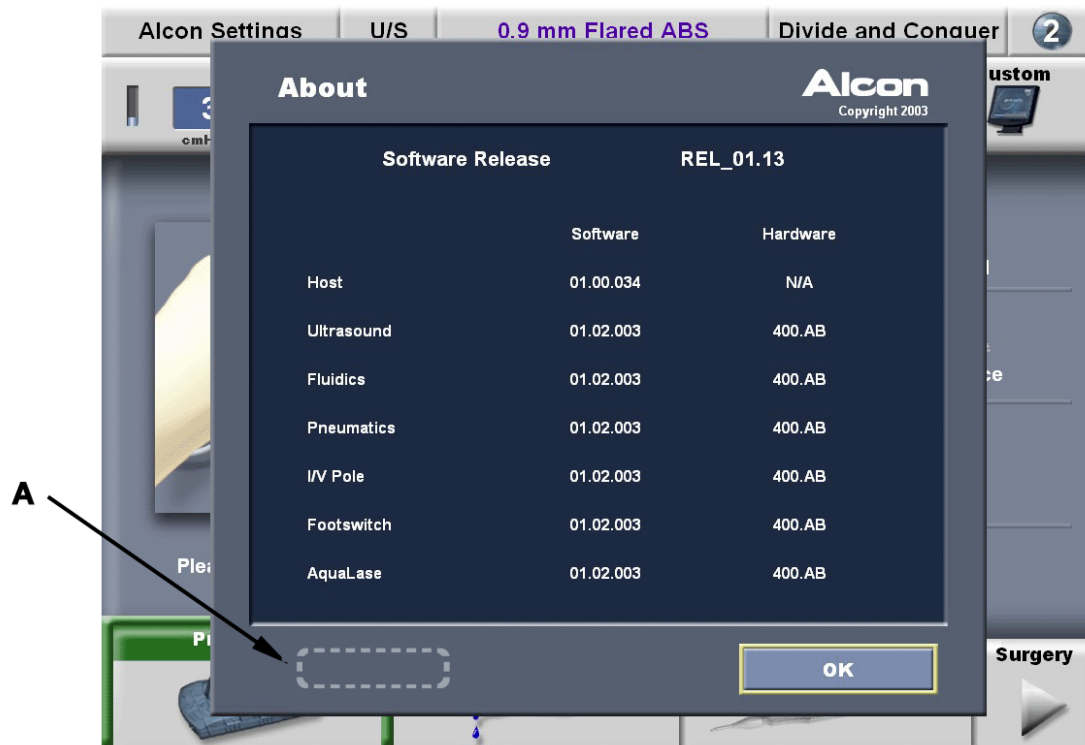
- 2.2.4.6 ☒ Verify that when the footswitch icon changes from 1 to 2 and 3, the footpedal detent vibration is felt accordingly.
- 2.2.4.7 ☒ Verify the appropriate triangle appears next to footswitch icon during the time each of the following switches is activated. Flex the footswitch cable during switch activation.
  - 2.2.4.7.1 left-vertical switch
  - 2.2.4.7.2 right-vertical switch
  - 2.2.4.7.3 left-horizontal switch
  - 2.2.4.7.4 right-horizontal switch
  - 2.2.4.7.5 left-horizontal treadle switch
  - 2.2.4.7.6 right-horizontal treadle switch

## 2.2.5 FLUIDICS SYSTEM TEST

### 2.2.5.1 TRANSDUCER ACCURACY - DRY TEST (Use Phaco FMS)

**NOTE: Do not prime FMS, perform following tests with dry "Phaco" FMS**

- 2.2.5.1.1 Install Phaco FMS. From Setup screen, select **Custom** then **About**. In the "About" window press **About** on the upper left corner, then press the area marked "A" in Figure 3 to access Service mode.

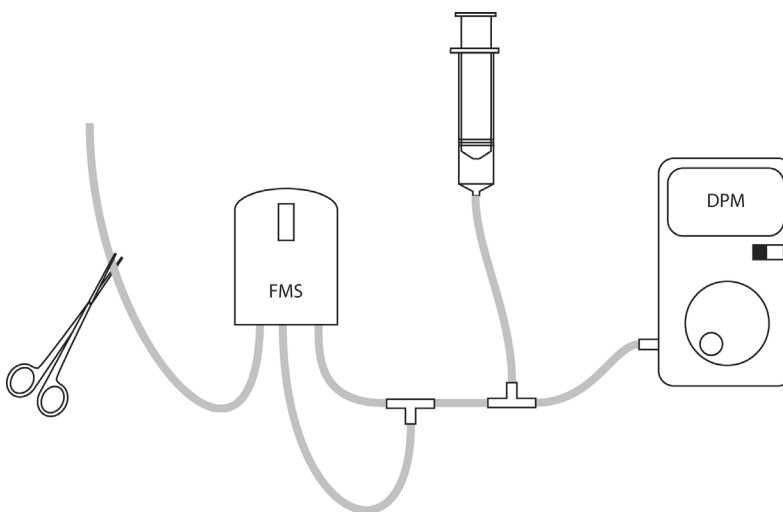


**Figure 3:** Touchscreen area for Service mode

- 2.2.5.1.2 Select Open Irrigation Valve button
- 2.2.5.1.3 Connect irrigation and aspiration luers to T fitting.
- 2.2.5.1.4 Connect syringe with tubing to T-fitting; connect DPM with T-fitting to T-fitting. (See Figure 4).

Status:	<i>Effective</i>	Supersedes:	<i>SOP-0637</i>
---------	------------------	-------------	-----------------

SOP Number: <b>ITCSOP-000637</b>	Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>	

**Figure 4: Transducer Accuracy**

2.2.5.1.5 Place hemostat on bottle spike tubing near FMS.

2.2.5.1.6 ☒ Pull/Push syringe; compare vacuum reading on system display to DPM meter at following settings:

**Note: Pull to get (-) readings, Push to get (+) readings.**

DPM	Irrigation	Aspiration
+100 ± 1 mmHg	+135 ± 14 cmH <sub>2</sub> O	+100 ± 10 mmHg
+50 ± 1 mmHg	+68 ± 7 cmH <sub>2</sub> O	+50 ± 10 mmHg
0 ± 1 mmHg	0 ± 7 cmH <sub>2</sub> O	0 ± 10 mmHg
-60 ± 1 mmHg	0 ± 7 cmH <sub>2</sub> O	-60 ± 10 mmHg
-200 ± 1 mmHg	0 ± 7 cmH <sub>2</sub> O	-200 ± 20 mmHg
-400 ± 1 mmHg	0 ± 7 cmH <sub>2</sub> O	-400 ± 40 mmHg
-600 ± 1 mmHg	0 ± 7 cmH <sub>2</sub> O	-600 ± 60 mmHg

2.2.5.1.7 Remove DPM, syringe, T-fitting, and hemostat.

2.2.5.1.8 Select Close Irrigation Valve button.

2.2.5.1.9 Remove FMS.

2.2.5.1.10 Select EXIT button, then "OK" button to return to Setup Screen.

#### 2.2.5.2 FMS PRIME – WET TEST

2.2.5.2.1 Select "Alcon Settings" and verify that the system recognizes either an Aqualase FMS or a Multipak FMS. Follow Screen Setup instructions.

**NOTE: Continue Wet Test with inserted FMS.**

2.2.5.2.2 Hang IV bottle and install drip chamber. Connect irrigation and aspiration luer together.

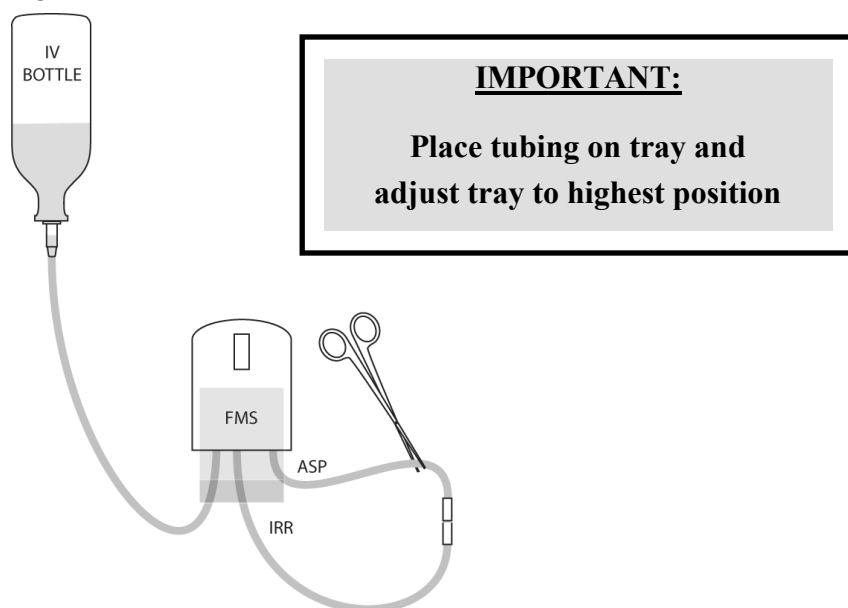
2.2.5.2.3 Press PRIME. Allow system to perform prime and perform vacuum check

**NOTE: Complete TEST sequence, which includes prime and vacuum check, requires about 1 minute.**

2.2.5.2.4 ☒ Verify that PRIME completes. If PRIME does not pass after three times, then replace FMS.

SOP Number: <b>ITCSOP-000637</b>	Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>	

### 2.2.5.3 OCCLUSION TEST



**Figure 5: Occlusion Test Setup**

- 2.2.5.3.1 ☒ Select Surgery, any Surgical Step and Fixed Vacuum. Perform the following steps at the given vacuum settings; verify after each occlusion that settled vacuum readings are in tolerance. For consistent testing, perform occlusion and record readings in following manner:

2.2.5.3.1.1 Press footswitch to position 3; let pump run until all air is purged from lines before clamping on Hemostat.

2.2.5.3.1.2 Clamp Hemostat onto Aspiration tubing (See Figure 5).

2.2.5.3.1.3 After system occludes (pump stops and "OCCLUSION" is displayed), wait 4-6 seconds for vacuum to stabilize before recording reading

VACUUM LIMIT	ASPIRATION RATE	Displayed Vacuum Readings (Front Panel)
6	12	0 to -16 mmHg
26	15	-16 to -36 mmHg
65	25	-55 to -75 mmHg
400	40	-360 to -440 mmHg
600	60	-540 to -660 mmHg

### 2.2.5.4 RESIDUAL PRESSURE

2.2.5.4.1 Select Fixed control of vacuum

2.2.5.4.2 Depress FTSW to position 3 and perform occlusion test at 100 mmHg vacuum setting (Bottle Height = 78 cm), then quickly release footswitch to position 0. Wait 3 seconds and record front panel reading.

2.2.5.4.3 ☒ Complete test for total of 3 readings:

**Verify readings are 0 mmHg ( $\leq 15$  mmHg).**

2.2.5.4.4 ☒ Repeat test at 400 mmHg vacuum setting for total of 3 readings.

**Verify readings are 0 mmHg ( $\leq 15$  mmHg).**

2.2.5.4.5 ☒ Repeat test at 600 mmHg Vacuum setting for total of 3 readings:

**Verify readings are 0 mmHg ( $\leq 15$  mmHg).**

Status:	<i>Effective</i>	Supersedes:	<i>SOP-0637</i>
---------	------------------	-------------	-----------------



SOP Number: <b>ITCSOP-000637</b>	Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>	

#### 2.2.5.5 ASPIRATION FLOW RATE

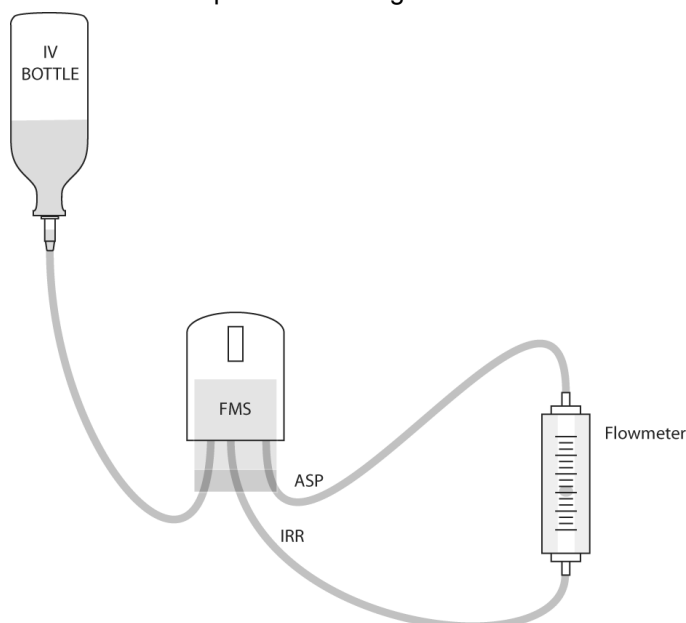
**NOTE: Indicate test method used to verify flow rates; flowmeter or beaker (these two different methods are noted below).**

2.2.5.5.1 ☒ When Asp Rate is set at 35 cc/min, verify flow rate is between 30-40 cc/min.

2.2.5.5.2 ☒ When Asp Rate is set at 25 cc/min, verify flow rate is between 21-29 cc/min.

##### 2.2.5.5.3 Test method using flow meter

2.2.5.5.3.1 Connect aspiration and irrigation lines to Flow Meter as shown in Figure 6.



**Figure 6:** Aspiration Flow Rate Test Setup Using Flow Meter

2.2.5.5.3.2 Select **Cortex** mode, Fixed vacuum. Perform PRIME if necessary to remove any air bubbles from irrigation, aspiration and drainage lines. Check flow rate of 35 cc/min. as follows:

2.2.5.5.3.2.1 Adjust **Asp Rate** to 35 cc/min.

2.2.5.5.3.2.2 Fully depress footswitch and hold until ball reaches most stable point.

2.2.5.5.3.3 Check flow rate of 25 cc/min. as follows:

2.2.5.5.3.3.1 Adjust **Asp Rate** to 25 cc/min. using up/down arrows.

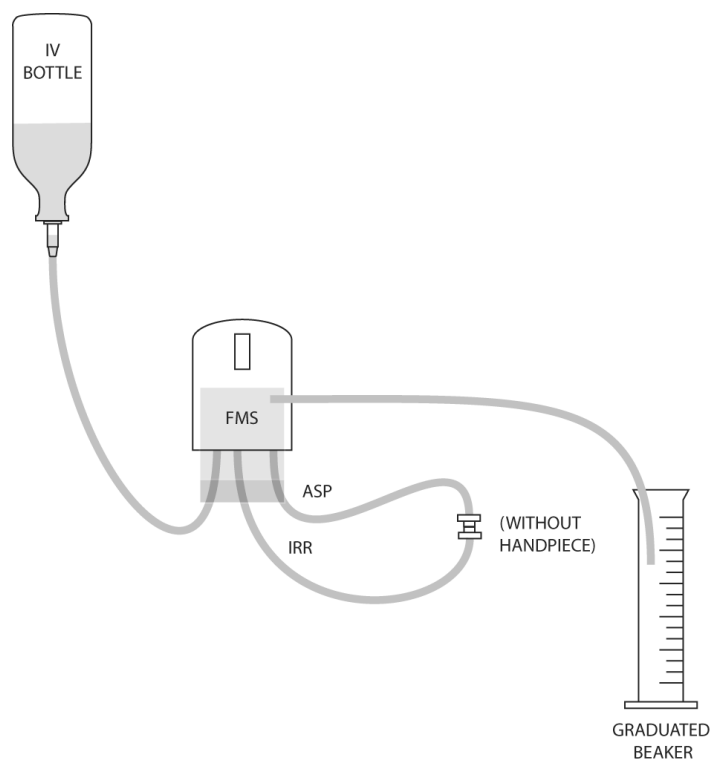
2.2.5.5.3.3.2 Fully depress footswitch and hold until ball reaches most stable point.

##### 2.2.5.5.4 Test method using graduated beaker.

2.2.5.5.4.1 Connect Aspiration and Irrigation lines together (See Figure 7).

Status:	<i>Effective</i>	Supersedes:	<i>SOP-0637</i>
---------	------------------	-------------	-----------------

SOP Number: <b>ITCSOP-000637</b>	Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>	



**Figure 7:** Aspiration Flow Rate Test Setup Using Graduated Beaker

- 2.2.5.5.4.2 Place drainage tube into dry Graduated Beaker.
- 2.2.5.5.4.3 Select **Cortex, fixed** control of aspiration rate; fully depress FTSW to remove air in tubing. Check flow rate as follows:
- 2.2.5.5.4.4 Adjust **Asp Rate** to 35 cc/min using up/down arrows.
- 2.2.5.5.4.5 Fully depress footswitch and hold for 60 seconds: Verify beaker volume: 30-40.
- 2.2.5.5.4.6 Empty Beaker. Select **Epi, fixed** control of aspiration rate; Check flow rate of 25 cc/min as follows:
- 2.2.5.5.4.7 Adjust **Asp Rate** to 25 cc/min using up/down arrows.
- 2.2.5.5.4.8 Fully depress footswitch and hold for 60 seconds: Verify beaker volume:  $25 \pm 4$  cc.

## 2.2.6 PNEUMATICS TEST

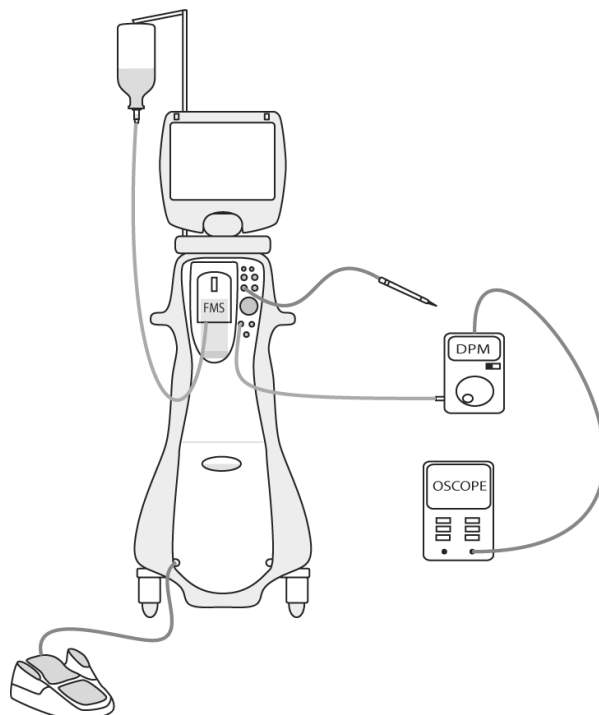
**NOTE:** This test can be performed using a Scopemeter interfacing with either the DPM III or Probe Drive Test Box. Indicate test method used on Service Checklist.

### 2.2.6.1 DPM III/SCOPEMETER METHOD

- 2.2.6.1.1 Connect tubing from the INFINITI™ VIT luer fitting to DPM per Figure 9. Set the DPM pressure range to -13.5 to 100 PSI.
- 2.2.6.1.2 Connect ¼" Phono Jack from DPM HI LEVEL OUT (100 mV=10 PSI) to Scopemeter Channel 1 per Figure 9. Set Scopemeter to measure 1:1 voltage at 100mV per div., trigger Channel 1 positive (+), DC, Time 20ms.
- 2.2.6.1.3 On INFINITI™ touch screen, select **Ant Vit** mode, then cut rate 50 CPM.
- 2.2.6.1.4 ☒ Press footswitch to position 3, **wait 10 seconds** for pressure to stabilize. Verify and record the peak voltage on the oscilloscope is above 231.84 mV (equivalent to 23.18 psi).

Status:	<i>Effective</i>	Supersedes:	<i>SOP-0637</i>
---------	------------------	-------------	-----------------

SOP Number: <b>ITCSOP-000637</b>	Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>	



**Figure 9: U/S & Pneumatic Test Setup (w/DPM shown)**

- 2.2.6.1.5 ☒ Vary the cut rate from 100 to 800 CPM at 100 increments. Verify the peak voltage is above 231.84 mV (equivalent to 23.18 psi) for each cut rate.

- 2.2.6.1.6 Remove tubing and test setup.

#### 2.2.6.2 PROBE DRIVE TEST BOX/SCOPEMETER METHOD

- 2.2.6.2.1 Select VIT mode and verify 800 cpm is the selected preset value
- 2.2.6.2.2 Connect appropriate tri-lumen test tubing to the INFINITI™ VIT luer fitting. Connect the other end to the Probe Drive test box "PRESSURE" Port.
- 2.2.6.2.3 Connect Phone Jack/BNC Cable between Probe Drive Box "OUTPUT" and Scopemeter Channel 1.
- 2.2.6.2.4 Set Scopemeter to measure 1:1 voltage at 500mV/DIV (500mV=10psi); trigger Channel 1 positive (+), DC, Time 10ms.
- 2.2.6.2.5 ☒ Press footswitch to position 3 and verify the peak output pulse indicates pressure out is >23psi.
- 2.2.6.2.6 Remove tubing and test setup.

#### 2.2.7 CAUTERY TEST

**NOTE: Prior to using the Cautery Test Load, perform the following procedure to verify the load box resistance.**

- 2.2.7.1 ☒ Ensure that the banana plugs of the Test Load are not connected to any jacks (open). Verify the resistance across the two test points of the Test Load is **75.0 ± 4ohms (71.0 to 79.0 ohms)**.
- 2.2.7.2 Insert Test Load banana plugs into cautery output jacks. Connect Scopemeter to output of the load using 10:1 probe.
- 2.2.7.3 Select COAG, **Fixed** mode and set **Coagulation Limit** to 100%.
- 2.2.7.4 ☒ Depress footswitch to position 2 and check oscilloscope frequency. Verify frequency of **1.43 to 1.67 MHz**.

Status:	<i>Effective</i>	Supersedes:	<i>SOP-0637</i>
---------	------------------	-------------	-----------------

SOP Number: <b>ITCSOP-000637</b>	Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>	

- 2.2.7.5 ☒ With footswitch in position 2, should get between **24.4V<sub>RMS</sub>** and **30.4V<sub>RMS</sub>**.
- 2.2.7.6 ☒ Set **Coagulation Limit** to 50% (footswitch in position 2). **Verify 17.4V<sub>RMS</sub>** and **21.4V<sub>RMS</sub>** (audible tone heard from unit).
- 2.2.7.7 ☒ Set **Coagulation Limit** to 25% (footswitch in position 2). **Verify 12.2V<sub>RMS</sub>** and **15.2V<sub>RMS</sub>** (audible tone heard from unit).
- 2.2.7.8 Release footswitch; disconnect Oscilloscope and Load Box

#### 2.2.8 PHACO AND NEOSONIX DRIVE TEST

##### 2.2.8.1 NeoSonix Load Box verification

**NOTE: If unable to use NeoSonix Load Box, check box ☒ and go to Customer Handpieces, step 2.2.9.**

- 2.2.8.1.1 ☒ Connect Infiniti™ adapter cable to NeoSonix load box. Check the resistance between the pin 9 (center pin) on the Lemo connector and test point labeled GND (black) on the load box. Must be from 2.37 KΩ to 2.62 kΩ.
- 2.2.8.1.2 ☒ Check the resistance between the test point labeled MOTOR OUTPUT (green) and GND. Must be between 9.5 Ω and 10.5Ω.
- 2.2.8.1.3 ☒ Check the resistance between the test point labeled MOTOR OUTPUT and MOTOR 1 (white). Must be between 9.5 Ω and 10.5Ω.
- 2.2.8.1.4 ☒ Check the resistance between the test point labeled MOTOR OUTPUT and MOTOR 2 (white). Must be between 9.5 Ω and 10.5Ω.

##### 2.2.8.2 Phaco Drive Test (system must be PRIMED)

- 2.2.8.2.1 Connect NeoSonix Load Box to the handpiece receptacle. Press **Setup**, then **Test Handpiece**.
- 2.2.8.2.2 Select **Ultrasound Continuous** mode, **Pre Phaco**, and set **U/S Power** to 50%, **Fixed**.
- 2.2.8.2.3 Set scopemeter to measure V<sub>RMS</sub> and frequency using 10:1 probe.
- 2.2.8.2.4 Connect the test lead to test point labeled U/S (red) and ground lead to GND on the NeoSonix Load Box.
- 2.2.8.2.5 Fully depress the footpedal then record the measured voltage and frequency.
  - 2.2.8.2.5.1 ☒ V<sub>RMS</sub> must be from 4.62 V<sub>RMS</sub> to 6.93 V<sub>RMS</sub>.
  - 2.2.8.2.5.2 ☒ Frequency must be from 33.5 kHz to 37.5 kHz.
- 2.2.8.2.6 Release the footpedal.

##### 2.2.8.3 NeoSonix Drive Test (system must be PRIMED)

- 2.2.8.3.1 Set the Scopemeter to measure V<sub>RMS</sub> and % of Duty Cycle.
- 2.2.8.3.2 Connect the Scopemeter positive test lead to the MOTOR (green) test point.
- 2.2.8.3.3 Select NeoSonix Continuous mode.
- 2.2.8.3.4 Set U/S Power to 0%, NeoSonix Threshold to 0% and NeoSonix Amplitude to 100%
- 2.2.8.3.5 Fully depress the footpedal and record the V<sub>RMS</sub> and % of Duty Cycle.
  - 2.2.8.3.5.1 ☒ V<sub>RMS</sub> must be from 1.785 V<sub>RMS</sub> to 3.775 V<sub>RMS</sub>.
  - 2.2.8.3.5.2 ☒ Percentage of Duty must be from 57% to 63% of duty Cycle.
- 2.2.8.3.6 Release the footpedal and disconnect the NeoSonix Load Box.

#### 2.2.9 CUSTOMER ULTRASONIC HANDPIECE CHECK

**(perform these tests if customer will provide the use of their handpieces or unable to use NeoSonix Load box)**

- 2.2.9.1 ☒ Perform the following steps to verify that each of the customers Phaco and/or NeoSonix handpieces tune and run. Record tested handpiece serial numbers.

Status:	<i>Effective</i>	Supersedes:	<i>SOP-0637</i>
---------	------------------	-------------	-----------------

SOP Number: <b>ITCSOP-000637</b>	Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>	

- 2.2.9.1.1 Install handpiece into appropriate connector on system. Attach irrigation and aspiration tubings to handpiece.
- 2.2.9.1.2 Install phaco tip and irrigation sleeve onto handpiece. Fill test chamber completely with liquid then slide over handpiece tip.
- 2.2.9.1.3 In Setup, press Test Handpiece to tune handpiece.
- 2.2.9.1.4 **Phaco Handpiece:** In Surgery, select Chop, then Ultrasound Continuous, power to 100%.
- 2.2.9.1.5 Depress footswitch to position 3 for 15 seconds. Verify Power indicates 100%.
- 2.2.9.1.6 Verify handpiece sound does not sputter or cut out while flexing the handpiece cable.
- 2.2.9.1.7 Select Ultrasound Pulse mode, set Limit to 100 and pulses rate to 10 pps.
- 2.2.9.1.8 Depress footswitch to position 3 for 15 seconds. Verify the pulsed phaco power sound is constant.
- 2.2.9.1.9 Repeat step 2.2.9.1.4 through 2.2.9.1.8 with other handpiece(s). Connect to 2<sup>nd</sup> U/S connector with at least one other handpiece.
- 2.2.9.1.10 **NeoSonix Handpiece:** In Surgery, select Chop, then NeoSonix Continuous, U/S power to 100%. Neosonix Amplitude to 50%, Neosonix Threshold to 50%
- 2.2.9.1.11 Depress footswitch to position 3 for 15 seconds. Verify indications reflect settings.
- 2.2.9.1.12 Verify handpiece sound does not sputter or cut out while flexing the handpiece cable.
- 2.2.9.1.13 Repeat step 2.2.9.10 through 2.2.9.1.12 with other handpiece(s). Connect to 2<sup>nd</sup> U/S connector with at least one other handpiece.

#### 2.2.10 **AQUALASE™ DRIVE AND PNEUMATIC TEST**

**NOTE: The system should already be primed from previous steps. If Multipak was previously used, replace with Aqualase FMS before proceeding. After a successful prime, go to the Surgery screen, leaving the Aqualase™ bottle line disconnected.**

**NOTE: If unable to use Aqualase Load Box, check box ☒ and go to Customer Handpieces, step 2.2.11.**

##### 2.2.10.1 AQUALASE FMS, LOADBOX, AND BOTTLE ADAPTER

- 2.2.10.1.1 ☒ On the Aqualase Load Box, check the resistance between the center pin of the BNC connector and the outer shell of the BNC connector. Must be from 25Ω +/- 2Ω.
- 2.2.10.1.2 Select Aqualase handpiece. Enter OK after the notification screen displayed.
- 2.2.10.1.3 Connect bottle adapter to Aqualase receptacle and connect line to DPM with psi settings selected.
- 2.2.10.1.4 ☒ Connect Aqualase Load Box connector and verify system LCD displays "Aqualase Test Tuned"

##### 2.2.10.2 AQUALASE LOAD BOX USAGE

- 2.2.10.2.1 Using a BNC cable, connect the Aqualase load Box to a Scopemeter.
- 2.2.10.2.2 Scopemeter settings:
  - 1:1 Probe
  - 50V AC per division (vert)
  - 500ns per division (horiz)
  - trigger: positive, 2 delay
- 2.2.10.2.3 Select **MAGNITUDE LINEAR** (/) control; MAGNITUDE limit 100.
- 2.2.10.2.4 Select pulse rate 50pps.
- 2.2.10.2.5 Select **BURST LINEAR** (/); **BURST** Limit to 100.
- 2.2.10.2.6 ☒ Press footswitch to start of position 3, then slowly press to limit of travel. Verify:

Status:	<i>Effective</i>	Supersedes:	<i>SOP-0637</i>
---------	------------------	-------------	-----------------

SOP Number: <b>ITCSOP-000637</b>	Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>	

- MAGNITUDE varies from 0 to 100%
- PULSE displays 50pps
- BURST varies from 0 to 100%

2.2.10.2.7 ☒ Press footswitch to bottom of position 3 and verify the following readings:

- Scopemeter reading above 280v peak to peak
- DPM reading above 5 psi

2.2.10.2.8 If Aqualase waveform has irregularities or spurious peaks and does not appear similar to Figure 10 below, record the condition as **S21002**, "Aqualase Waveform Nonuniformity" and replace the Aqualase Controller PCB.

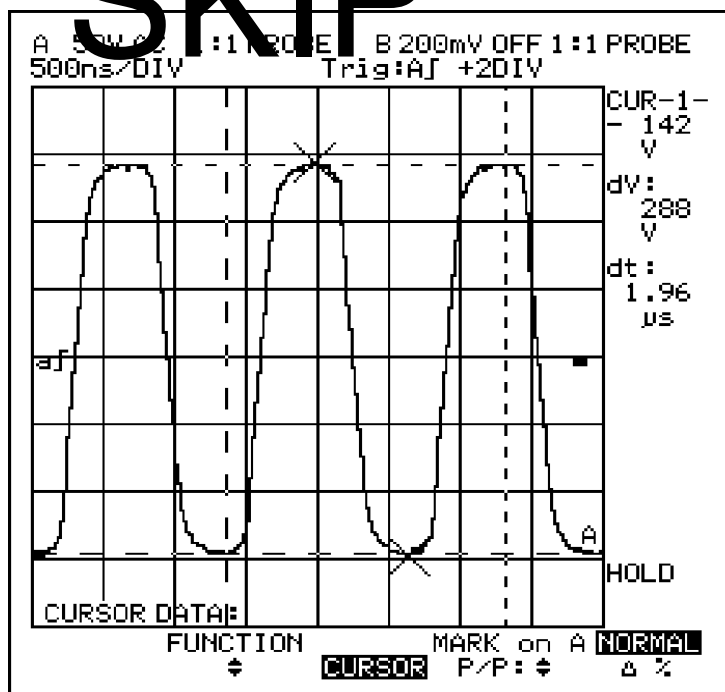


Figure 10: Aqualase Test Waveform

**NOTE: Do not apply power to Aqualase™ Load Box for more than 30 seconds continuously. Damage to load box may occur as a result of overheating.**

#### 2.2.11 CUSTOMER AQUALASE™ HANDPIECE TEST

**NOTE: Perform these tests if customer will provide the use of their handpieces or unable to use Aqualase™ Load Box.**

##### 2.2.11.1 HANDPIECE, FMS, AND CONTAINER (Select SETUP)

- 2.2.11.1.1 Select Aqualase™ Handpiece. Enter OK after the notification screen is displayed.
- 2.2.11.1.2 Connect Aqualase™ Handpiece to Aqualase™ connector
- 2.2.11.1.3 Install Aqualase™ BSS container.

##### 2.2.11.2 AQUALASE™ HANDPIECE TUNING

- 2.2.11.2.1 Connect Aqualase™ black tubing to BSS container and connect black luer fitting to handpiece.
- 2.2.11.2.2 ☒ Press "Test handpiece" button to tune handpiece and perform flow check. **Tuning takes about 10-12 sec.** Verify handpiece passes tune.

##### 2.2.11.3 AQUALASE™ HANDPIECE USAGE

Status:	Effective	Supersedes:	SOP-0637
---------	-----------	-------------	----------

SOP Number: <b>ITCSOP-000637</b>	Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>	

- 2.2.11.3.1 Select Surgery mode, **MAGNITUDE LINEAR (/)** Control; **MAGNITUDE** limit 100.
- 2.2.11.3.2 Select pulse rate 50 pps.
- 2.2.11.3.3 Select **BURST LINEAR (/)** control; **BURST** Limit to 100.
- 2.2.11.3.4 ☒ Press footswitch to start of position 3, then slowly press to limit of travel. Verify:
- MAGNITUDE varies from 0 to 100%.
  - PULSE displays 50pps
  - BURST varies from 0 to 100%
  - AquaLase™ Handpiece buzzing sound indicates power is applied to handpiece.
  - Pneumatic pump is occasionally on
- 2.2.11.3.5 Select **MAGNITUDE Fixed (---)** control; **MAGNITUDE Limit** at 100
- 2.2.11.3.6 Select **BURST Fixed (---)** control; **BURST Limit** at 100.
- 2.2.11.3.7 Select pulse rate 50 pps.
- 2.2.11.3.8 ☒ Press footswitch to position 3.
- MAGNITUDE displays 100%
  - PULSE displays 50 pps
  - BURST displays 100%
  - AquaLase™ Handpiece buzzing sound indicates power is applied to handpiece.
  - Pneumatic pump is occasionally on

## 2.2.12 BATTERY BACKUP TEST

- 2.2.12.1 With the system powered up and the Infiniti application open (i.e., Setup or Surgery screen), unplug the system from the wall outlet.
- 2.2.12.2 ☒ Assure system closes Windows® and shuts down between 5 seconds and 1 minute. (Note: Plug system back into power outlet).

## 2.2.13 VIDEO OUTPUT TEST

**NOTE: The following test is to be performed during the initial installation of a system or during Preventive Maintenance (step 2.1.14). It is not necessary to complete after repairs unrelated to video output are made.**

- 2.2.13.1 Connect keyboard to the system.
- 2.2.13.2 Connect DB9 Interface PCB, p/n 210-2305-501, to the top DB9 connector serial port (below the USB connector) on the rear panel.
- 2.2.13.3 Connect a jumper wire between test points 2 & 3 on the PCB. The test points on the PCB correspond to the connector pins
- 2.2.13.4 Insert the Service CD either within one minute of turning the system on or before turning the system off/on. The system should boot-up in Windows™.
- 2.2.13.5 From the Windows™ Start menu select Run and type in **hypertrm**. Press Enter or select OK from the touchscreen
- 2.2.13.6 If HyperTerminal has never been run before a dialog titled **Local Information** will appear (if the **Local Information** dialog does not appear skip to step 2.2.13.8). In the **area code** input field, enter **949**. No other changes need to be made. Press Enter or select OK.
- 2.2.13.7 In the **Phone And Modem Options** dialog press Enter or select **OK**.
- 2.2.13.8 In the **Connection Description** dialog enter **COM Test** under **Name**, then press Enter or select **OK**.
- 2.2.13.9 In the **Connect To** dialog under **Connect Using** drop-down box ensure that **COM1** is selected, then press Enter or select **OK**.

O  
P  
T  
I  
O  
N  
A  
L

Status:	<i>Effective</i>	Supersedes:	<i>SOP-0637</i>
---------	------------------	-------------	-----------------

SOP Number: <b>ITCSOP-000637</b>	Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>	

# OPTIONAL

- 2.2.13.10 In the **COM1 Properties** dialog under the **Flow Control** drop-down box, select **None**. No other changes need to be made. Press Enter or select **OK**.
- 2.2.13.11 ☒ Verify that characters typed on keyboard appear on Hyperterminal portion of the display. While the interface PCB and jumper are connected to the serial port, you should see any characters typed into the terminal. If the interface PCB and jumper are not connected, then you should not see any characters typed into the terminal.
- 2.2.13.12 Select File, then Exit (or Alt+F4) to close HyperTerminal. Select **Yes** if prompted to disconnect from the session. Select **No** if prompted to save the current session.
- 2.2.13.13 Remove Service CD from drive.
- 2.2.13.14 From Windows™ Start menu, select Shut Down from the drop down menu and select OK.
- 2.2.13.15 Disconnect keyboard and interface PCB with jumper wire from console.
- 2.2.14 **SYSTEM SHUT DOWN**
  - 2.2.14.1 Turn system back on after BACKUP TEST.
  - 2.2.14.2 Disconnect irrigation and aspiration lines from handpiece (if necessary) and connect together.
  - 2.2.14.3 Remove irrigation bottle and flip holder into storage position, then remove and drain the FMS.
  - 2.2.14.4 Turn system off at Standby switch, then Main.
- 2.2.15 **HISTORY LOG ENTRY**
  - 2.2.15.1 ☒ Make appropriate entry on log sheet, located on the backside of battery cover behind the footswitch drawer.

## 3 RESPONSIBILITY

- 3.1 The responsibility for adhering to this procedure lies with all personnel of the service organization qualified to perform service on the Infiniti™ Vision System. It is the responsibility of management personnel to insure compliance.

## 4 DEFINITIONS

- 4.1 **COAG** – Coagulation
- 4.2 **CPC** – Brand-name of pneumatic connector type
- 4.3 **CPM** – Cuts per Minute
- 4.4 **DPM** – Digital Pressure Meter
- 4.5 **DVM** – Digital Volt Meter
- 4.6 **FMS** – Fluidic Module System
- 4.7 **FTSW** – Footswitch
- 4.8 **GND** – Ground
- 4.9 **LCD** – Liquid Crystal Display
- 4.10 **PCB** – Printed Circuit Board
- 4.11 **USB** – Universal Serial Bus

## 5 SOPS / FORMS / JOB AIDS / REFERENCES

- 5.1 **SOPS**
  - 5.1.1 ITCSOP-000040, *ITC Records Retention Program*
- 5.2 **FORMS**
  - 5.2.1 ITCD0C-000360, *Data Sheet for Infiniti Vision System*

Status:	<i>Effective</i>	Supersedes:	<i>SOP-0637</i>
---------	------------------	-------------	-----------------



SOP Number: <b>ITCSOP-000637</b>	Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>	

### 5.3 REFERENCES

5.3.1 N/A

## 6 REVISION NOTES

- 6.1 Removed reference to signing of Data Sheet in Section 1.2
- 6.2 Note in 2.1, recommend PM once a year
- 6.3 Added battery replacements, Section 2.1.15 and 2.1.16
- 6.4 Section 2.2.3.3.4, changed Ultrasonic to Ultrasound
- 6.5 Added 2.2.10.2.8, Aqualase Waveform comparison instructions
- 6.6 Section 2.2.13.6 contains reference to step. Corrected reference from 2.2.12.8 to 2.2.13.8

## 7 RECORDS RETENTION

- 7.1 Records are retained and protected in accordance with ITCSOP-000040, *ITC Records Retention Program*.

## 8 DOCUMENT HISTORY

Document	Rev.	Effective	Title
ITCSOP-000637	2.0	02/04/05	STP - Infiniti Vision System
ITCSOP-000637	1.0	09/24/04	STP - Infiniti Vision System
SOP-0637	02	02/20/04	STP - Infiniti <sup>TM</sup> Vision System
SOP-0637	01	08/08/03	STP - Infiniti <sup>TM</sup> Vision System
SOP-0637	00	05/23/03	STP - Infiniti <sup>TM</sup> Vision System

## 9 APPENDIXES

9.1 N/A

**END OF DOCUMENT**

Status:	<i>Effective</i>	Supersedes:	<i>SOP-0637</i>
---------	------------------	-------------	-----------------

SOP Number: <b>ITCSOP-000637</b>		Version: <b>, CURRENT, 4.0</b>	Effective Date: <b>25-Aug-2006</b>
Title:	<b>STP - Infiniti Vision System</b>		

## Approval Page

**Date/Time**

**(mm/dd/yyyy GMT):**

**Signed by:**

**Justification:**

08/04/2006 20:46:20

Michael Fitzpatrick

PRO's Management Approval

08/04/2006 21:01:10

Rob Riccardi

Functional Area Approval

08/07/2006 21:50:27

Russ Ford

Functional Area Approval

08/09/2006 15:55:30

Ed Richards

Functional Area Approval

08/23/2006 17:29:31

James Zunino

Functional Area Approval

08/23/2006 18:17:49

Darrell Branine

PRO Approval

Status:	<i>Effective</i>	Supersedes:	<i>SOP-0637</i>
---------	------------------	-------------	-----------------